NOTICE OF REASSESSMENT FOR *ESCHERICHIA COLI* O157:H7 CONTROL AND COMPLETION OF A CHECKLIST FOR ALL BEEF OPERATIONS

NOTE: FSIS will be mailing one hardcopy of the full notice with attachments to the management official at the establishment and one to the Inspector-in-Charge (IIC). The IIC also will receive a CD copy of training material related to implementation of this notice.

I. PURPOSE

The purpose of this notice is to make inspection program personnel aware of a number of significant developments involving *Escherichia coli* O157:H7 (*E. coli* O157:H7) in beef products that occurred since the beginning of the high prevalence season for this pathogen in April. These developments raise questions about the adequacy of the interventions and controls that beef operations (i.e., official establishments that slaughter, fabricate, grind, mechanically tenderize, or enhance by tumbling, massaging, or injecting beef products such as with marinades) are employing to address this pathogen. Because these developments have come so swiftly, however, it seems likely that most establishments are not aware of the full extent of the problems evidenced by these developments. As a result, many establishments have not considered the implications of these developments for their Hazard Analysis and Critical Control Points (HACCP) systems.

This notice summarizes these significant developments and instructs inspection program personnel to meet with the establishment, to review the developments at that meeting, and to advise the establishment that these developments constitute changes that could affect the establishment's hazard analysis or cause the establishment to alter its HACCP plan. Inspection program personnel are to inform the establishment management that, given these facts, under 9 CFR 417.4(a)(3), it has an obligation to reassess its HACCP system to determine whether any changes are necessary in response to these developments (see Attachment 1). This notice also instructs inspection program personnel to determine what changes, if any, the establishment made on the basis of its reassessment. Inspection program personnel are to document their findings in the Responses to the Reassessment found in Attachment 3.

In addition, inspection program personnel at official establishments that slaughter, fabricate, grind, mechanically tenderize, or enhance by tumbling, massaging, or injecting beef products such as with marinades are to complete an on-line checklist on how the establishment addresses *E. coli* O157:H7 (see draft checklist Attachment 5). For the purposes of this notice, such establishments are considered beef operations. The section of the checklist titled "Raw Beef Food Safety System" identifies a set of best practice measures that, while not required, the Agency considers to be essential to controlling *E. coli* O157:H7. The remainder of the checklist describes known control measures and activities employed by beef operations that may affect the level of control employed by the establishment. FSIS is capturing all this information for each establishment and will use the information to determine targeted approaches for the risk-based verification testing program by FSIS and to assist in prioritizing the scheduling of Food Safety Assessments by the Enforcement, Investigation, and Analysis Officer (EIAO) in each District Office (DO).

Before inspection program personnel submit the online checklist to the Policy

Analysis Division, Office of Policy, Program, and Employee Development (PAD/OPPED), they are to share a copy with a management official at the establishment. The management official will be given the opportunity to correct any response for which a change can be substantiated. If the Front-line Supervisor has concerns or changes to the checklist, it may be modified and re-submitted to PAD/OPPED. Also, periodically, FSIS will instruct inspection program personnel to review the checklist data and update it.

II. BACKGROUND

FSIS has issued two FR Notices since 2002 specifically mandating the reassessment of HACCP plans related to *E. coli* O157:H7 control measures. In October 2002, FSIS issued a FR Notice that outlined adulteration considerations regarding intact and non-intact beef products. This reassessment was a consequence of new scientific data identifying the increased prevalence of this pathogen on live cattle coming to slaughter and the results from FSIS' *E. coli* O157:H7 testing program since FSIS began using a new testing method. In addition, this 2002 FR Notice described at length the Agency's expectations regarding the appropriate use of prerequisite (or purchase specification) programs (see: http://www.fsis.usda.gov/OPPDE/rdad/FRPubs/00-022N.pdf or for hard copy only Attachment 6 -- 67 FR 62325, October 7, 2002).

In May 2005, FSIS again issued a FR Notice that outlined adulteration considerations regarding mechanically tenderized and enhanced beef products. This 2005 FR Notice informed beef operations about three known outbreaks associated with such products (see: http://www.fsis.usda.gov/OPPDE/rdad/FRPubs/04-042N.pdf or for hard copy only Attachment 7 -- 70 FR 30331, May 26, 2005).

Beginning at least with the high prevalence season for *E. coli* O157:H7 in April 2007, some control measures for *E. coli* O157:H7 implemented by beef operations have proven to be inadequate. During this period, there has been an increased number of positives in Agency sampling for *E. coli* O157:H7, compared to the preceding three years, a couple of outbreaks attributed to this pathogen and beef products, and a number of large recalls. This situation requires a broad reassessment of how beef operations and FSIS are assessing this pathogen.

III. INSPECTION PROGRAM PERSONNEL RESPONSIBILITIES

A. Awareness Meeting

1. Within one week of receipt of the initial receipt of this notice, inspection program personnel at all beef operations are to conduct an awareness meeting with a management official of the establishment. At the meeting, inspection program personnel are to discuss:

a. the developments identified in Attachment 2, Developments That Support That There Is A Need For Establishments To Reassess Their HACCP Plans;

b. the documents referenced in this notice, including the Response to the Reassessment and the *E. coli* O157:H7 Checklist. Inspection program personnel are to inform the management that the *E. coli* O157:H7 Checklist (Attachment 5) is a draft of the checklist and there will be differences between it and the final version that will be completed by inspection program personnel; and

c. that the reassessment of the HACCP plan should be conducted by **October 26, 2007**.

2. Inspection program personnel are to prepare a memorandum of interview for the awareness meeting, documenting the following:

a. who was present at this initial awareness meeting;
b. the date and time of the meeting;
c. what was discussed, and
d. any documents that were shared with the management official.

3. Inspection program personnel are to maintain a copy of the memorandum in the official government file and provide a copy to the establishment management.

B. Verification Responsibilities

1. At the next weekly meeting after October 26, 2007, inspection program personnel are to ascertain whether and how the establishment reassessed. Inspection program personnel are to complete the questions in Attachment 3, Responses to the Reassessment, and submit the answers by no later than **November 2, 2007**.

2. Inspection program personnel are to complete the reassessment questions in Attachment 3 in lieu of performing a food safety 01 or 02 procedure. To determine the product for which the scheduled 01 or 02 will not be performed, inspection program personnel are to use the chart in Attachment 4. Procedures for products with the lowest risk factor are to be replaced first.

3. Inspection program personnel are to save the answers to Attachment 3 in a Word document. Inspection program personnel are to maintain a copy of Responses to the Reassessment in the official government file, provide a copy to the establishment management, and, e-mail the Word document to:

a. the Front-line Supervisor,

b. District Analyst in the District Office, and

c. PAD/OPPED at: O157H7EstablishmentPractices@fsis.usda.gov or at: O157H7 Establishment Practices (found in Outlook).

NOTE: If inspection program personnel or the FLS have concerns regarding the

reassessment, they may contact the DO. The DO will determine whether to schedule a Comprehensive Food Safety Assessment at the establishment.

4. OPPED will develop a summary report, by District, listing completed and pending Responses to the Reassessment and provide that to the OFO management for their follow up.

C. Completing *E. coli* O157:H7 Checklist

1. Although a draft copy of the checklist is Attachment 5, inspection program personnel are not to complete this checklist because there will be changes. Inspection program personnel are only to review this checklist to determine whether they have any questions. Inspection program personnel are to direct any questions to the Policy Development Division.

2. After inspection program personnel have reviewed the *E. coli* O157:H7 Checklist, they are to complete the training regarding the *E. coli* O157:H7 Checklist on the provided CD. Inspection program personnel are allotted up to two hours of 01 time to complete the training. After completing the training, inspection program personnel will take a test on Aglearn. The Resources Management Analyst will run a weekly training report for the Deputy District Managers to verify that inspection program personnel have completed the training.

3. Inspection program personnel will receive an email containing instructions for completing the checklist, an attached copy of the checklist in Word format that can be completed, printed and saved, and a link to an Intranet site where they are expected to complete the online checklist.

4. Inspection program personnel are first to complete the checklist in a Word document (**NOTE**: printing it and completing it on a printed hardcopy may be helpful because some of the information will be available only from reviewing records).

5. Inspection program personnel are to share a printed or electronic copy with the establishment management and provide them 48 hours to correct any responses for which it can substantiate the changes.

6. Inspection program personnel are to save the Word document and e-mail it to their District Analyst.

7. Inspection program personnel are to go to the provided link and enter the information from the completed checklist online for official submittal of the results.

NOTE: The instructions for the checklist will explain how to complete the checklist in multiple shift establishments.

8. Inspection program personnel are to complete steps 1-7 by **November 30, 2007**. Inspection program personnel are to the use result code “U-Performed PE/Checklist” to indicate when they have completed the *E. coli* O157:H7 PERSEUS checklist in lieu of performing a food safety 01 or 02 procedure. To determine the product for which the scheduled 01 or 02 will not be performed, inspection program

personnel are to use the chart in Attachment 4. Procedures for products with the lowest risk factor are to be replaced first.

9. After completing the *E. coli* O157:H7 Checklist, inspection program personnel are to maintain a copy of it in the official government file and provide a copy to the establishment management.

10. Before **November 30, 2007**, Front-line Supervisors are to check that inspection program personnel have accurately completed the checklist. If the Front-line Supervisor finds inconsistencies in a checklist, he or she should contact PDD to discuss how to submit a revised checklist.

11. OPPED will have weekly reports developed by district, listing the establishments for which they have received completed *E. coli* O157:H7 checklists and establishments for which they have not received the checklist. OPPED will provide those weekly reports to OFO management.

12. Periodically, FSIS will instruct inspection program personnel to review the prior submitted checklist and to update it, if appropriate, and ensure that the updated information is submitted to PAD/OPPED.

Sec. 417.4 Validation, Verification, Reassessment.

(a) Every establishment shall validate the HACCP plan's adequacy in controlling the food safety hazards identified during the hazard analysis, and shall verify that the plan is being effectively implemented.

(1) Initial validation. Upon completion of the hazard analysis and development of the HACCP plan, the establishment shall conduct activities designed to determine that the HACCP plan is functioning as intended. During this HACCP plan validation period, the establishment shall repeatedly test the adequacy of the CCP's, critical limits, monitoring and recordkeeping procedures, and corrective actions set forth in the HACCP plan. Validation also encompasses reviews of the records themselves, routinely generated by the HACCP system, in the context of other validation activities.

(2) Ongoing verification activities. Ongoing verification activities include, but are not limited to:

(i) The calibration of process-monitoring instruments;

(ii) Direct observations of monitoring activities and corrective actions; and

(iii) The review of records generated and maintained in accordance with Sec. 417.5(a)(3) of this part.

(3) Reassessment of the HACCP plan. Every establishment shall reassess the adequacy of the HACCP plan at least annually and whenever any changes occur that could affect the hazard analysis or alter the HACCP plan. Such changes may include, but are not limited to, changes in: raw materials or source of raw materials; product formulation; slaughter or processing methods or systems; production volume; personnel; packaging; finished product distribution systems; or, the intended use or consumers of the finished product. The reassessment shall be performed by an individual trained in accordance with Sec. 417.7 of this part. The HACCP plan shall be modified immediately whenever a reassessment reveals that the plan no longer meets the requirements of Sec. 417.2(c) of this part.

(b) Reassessment of the hazard analysis. Any establishment that does not have a HACCP plan because a hazard analysis has revealed no food safety hazards that are reasonably likely to occur shall reassess the adequacy of the hazard analysis whenever a change occurs that could reasonably affect whether a food safety hazard exists. Such changes may include, but are not limited to, changes in: raw materials or source of raw materials; product formulation; slaughter or processing methods or systems; production volume; packaging; finished product distribution systems; or, the intended use or consumers of the finished product.

Developments That Support That There Is a Need for Establishments to Reassess Their HACCP Systems

A. Adverse trend in percent positive rate in FSIS verification testing

1. FSIS monitors the percent positive rate (i.e., the percentage of raw ground beef samples analyzed by FSIS that are found positive for *E. coli* O157:H7). In addition, FSIS has established a maximum target percent positive rate of 0.200% at any time in the calendar year (CY) or fiscal year (FY). Generally, FSIS reports the percent positive rate in two ways. For the public, FSIS has reported a CY status at the end of the CY. For internal budget considerations, FSIS reports the percent positive rate on a FY quarter and annual basis. FSIS believes that by tracking the day-to-day changes in the percent positive rate, whether by CY or FY, the data provide useful indications about changes in beef operations. In addition, FSIS uses these data to measure changes in the degree of control exerted by beef operations for ensuring that *E. coli* O157:H7 is non-detectable in verification samples collected by FSIS.

2. In CY2002, the percent of positive rate from raw ground beef samples collected by FSIS in Federal plants, retail stores, and at import houses was 0.787% (55 positives in 6,986 samples). Thereafter, there was a remarkable decrease in the percent positive rate for similarly collected samples. In CY2003, the percent positive rate dropped to 0.305% (20 positives in 6,553 samples, albeit slightly fewer samples than the prior CY). Since then through CY2006, there has been a persistent decrease in the percent positive rate even with a steady increase in the number of similar samples analyzed. Moreover, the maximum target percent positive rate of 0.200% has not been exceeded in any of the recent prior CYs.

3. However, thus far in CY2007, through October 10, 2007, FSIS found 20 *E. coli* O157:H7 positive samples, compared to twenty positive results for the entire CY06, as of today, the percent positive rate is 0.208. The last year that the percent positive rate exceeded the maximum percent positive target rate was CY2003. This uptick in the percent positive rate is cause for concern.

B. Unusual number of positive samples in a short span of time

In July 2007, FSIS found five positives in a span of three days. There was no linkage amongst the samples and no evidence of FSIS laboratory contamination. This is believed to be a rare event in the 13 year history of verification testing by FSIS for this pathogen. This finding presents a basis for concern that the control measures implemented by beef operations may not be adequate to address the degree of contamination by *E. coli* O157:H7.

C. Increased number of recalls associated with E. coli O157:H7

1. For CY2007 through October 6, 2007, FSIS already has requested 13 recalls involving about 29 million pounds of product associated with *E. coli* O157:H7. In contrast, there were eight recalls involving less than 200,000 pounds of product associated with *E. coli* O157:H7 for the entire CY2006.

2. FSIS compiled the factors that apparently contributed to the recalls of CY2007. Consistently, these establishments relied upon faulty decisions that did not fully account for the expectations noted by FSIS in either the October 2002 or May 2005 reassessments. The decision that were not sufficiently supported under 9 CFR 417.5, in one or more of the recent recalls, included:

a. identification of *E. coli* O157:H7 as a hazard not reasonably likely to occur in incoming beef without demonstrating the on-going effectiveness of the prerequisite program upon which this decision was based (e.g., not consistently testing incoming or finished product; not requiring incoming product to be tested using a consistent sampling design among all suppliers; and not demonstrating that the source material or the finished product would meet a standard of non-detectable for *E. coli* O157:H7 through production lot-specific Certificates of Analysis (COAs)).

b. identification of *E. coli* O157:H7 as a hazard not reasonably likely to occur in raw ground beef even though "bench trim," the boneless manufacturing trimmings generally derived from the sizing of primal/sub-primal cuts (steaks and roasts), was used as a component in the manufacture of raw ground beef; the primal/sub-primal cuts were not handled in the same manner as boneless manufacturing trimmings (i.e., verification of the effective application of antimicrobial treatments was not conducted nor was the primal/sub-primal cut or the bench trim derived from the primal/sub-primal cut tested for *E. coli* O157:H7 using any verification testing protocol before or after grinding).

c. identification of *E. coli* O157:H7 as a hazard not reasonably likely to occur in primal/sub-primal cuts intended for use in a mechanical tenderization process, and neither the primal/sub-primal cuts nor the derived bench trim were handled in a manner designed to ensure that *E. coli* O157:H7 was non-detectable.

D. Increased number of recalls specifically initiated as a consequence of human illness

As of October 6, 2007, of the 13 recalls related to *E. coli* O157:H7 in CY2007, 7 of these were initiated because of their association with human illness. FSIS recognizes the Healthy People 2010 food safety objective for *E. coli* O157:H7 infections (now referred to as shiga toxin-producing *E. coli* O157 or STEC O157 infections) as the public health goal. The 1997 baseline was 2.1 laboratory confirmed cases per 100,000 humans, while the 2010 target is 1.0 case per 100,000 humans. The most current result, represented by CY2006 FoodNet data, is 1.31 infections per 100,000 humans. This is up from 1.06 in 2005 and 0.90 in 2004, which was the only year in which the 2010 target was met. Since 2004, has been an adverse trend above the Healthy People 2010 target despite the FSIS percent positive rate achievements. Now that the CY2007 current percent positive rate is at or above the maximum target percent positive

rate, these apparent upticks are cause for significant concern.

E. Repetitive implication of certain source materials used in the production of ground beef found by FSIS to be positive for *E. coli* O157:H7 or involved in recalls:

1. In March, FSIS began testing boneless manufacturing trimmings. In addition, the Agency began tracking which components used in the production of raw ground beef were included in each production lot of ground beef tested by FSIS and found to be positive for *E. coli* O157:H7. Whenever one of these raw ground beef components was identified as part of the production lot found to be contaminated with *E. coli* O157:H7, FSIS conducted follow-up testing for that specific component, but only on a limited basis. Moreover, in recent recalls involving *E. coli* O157:H7, beef products other than boneless manufacturing trimmings were implicated.

2. Components beyond the traditional boneless manufacturing trimmings include: Two-piece chuck (a primal/sub-primal cut); head meat; cheek meat; weasand meat; heart meat; low temperature rendered beef (also referred to as lean finely textured beef); “specially handled beef” (a product treated with an antimicrobial and designated for grinding at retail via a purchase specification arrangement with the retailer); and meat from advanced meat recovery systems (AMR).

3. Based on this information, FSIS has reason to believe that establishments are not effectively ensuring that *E. coli* O157:H7 is adequately controlled at the slaughter and fabrication operations (i.e., suppliers to grinders). This development is cause for significant concern.

RESPONSES TO THE REASSESSMENT

Inspection program personnel are to answer the following questions as either yes or no and then provide specific and brief information where requested. Inspection program personnel are to obtain answers to these questions by reviewing the establishment's food safety system records.

1. Did the establishment reassess its HACCP plan(s) based on the developments as set out in section III above:

Yes ___ No ____

2. Did the establishment change its HACCP plans as a result of the reassessment:

Yes ___ No ____

a. If yes, describe the change.

b. If no, provide the establishment's reason for not making a change.

3. Did the establishment change its Sanitation SOP(s) as a result of the reassessment.

Yes ___ No ____

a. If yes, describe the change.

b. If no, provide the establishment's reason for not making a change.

4. Did the establishment change its other prerequisite programs as a result of the reassessment.

Yes ___ No ____

a. If yes, describe the change.

b. If no, provide the establishment's reason for not making a change.

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5. To the best of your ability, estimate how long it took to complete these questions?

Product/Process Risk

NOTE: The products are listed in descending order of risk.

FINISHED PRODUCT TYPE	ISP Code
Raw intact beef	03C
Raw intact pork	03C
Raw intact meat – other	03C
Raw intact chicken	03C
Raw intact turkey	03C
Raw intact poultry – other	03C
Raw ground, comminuted, or otherwise non-intact beef	03B
Raw ground, comminuted, or otherwise non-intact pork	03B
Raw ground, comminuted, or otherwise non-intact meat – other	03B
Raw ground, comminuted, or otherwise non-intact chicken	03B
Raw ground, comminuted, or otherwise non-intact turkey	03B
Raw ground, comminuted, or otherwise non-intact poultry -- other	03B
Raw otherwise processed meat	03E, 03H,03I
Raw otherwise processed poultry	03E, 03H,03I
RTE fermented meat (without cooking)	03E
RTE fermented poultry (without cooking)	03E
RTE dried meat	03E, 03F
RTE dried poultry	03E, 03F
RTE salt-cured meat	03E, 03I
RTE salt-cured poultry	03E, 03I
RTE fully-cooked meat	03G
RTE fully-cooked poultry	03G
RTE meat, fully-cooked, without subsequent exposure to the environment	03G
RTE poultry, fully-cooked, without subsequent exposure to the environment	03G

Attachment 5

E. coli O157:H7 Checklist

FOR REVIEW PURPOSES ONLY.

NOTE: This is a draft of the checklist, and there will be differences between it and the final version.

FSIS is collecting information on the control measures for Escherichia coli O157 (E. coli O157:H7) beef operations (i.e., official establishments that slaughter, fabricate, grind, mechanically tenderize, or enhance by tumbling, massaging, or injecting solutions such as marinades) use during the production of raw beef product. The Agency will use the information for a number of purposes, including:

● To identify those beef operations that are not employing certain **INTERRELATED** practices that FSIS has identified as being established as directly contributing to control of this pathogen (designated as "BP" for "best practices" in the section of the checklist titled "B-Raw Beef Food Safety System"). See the compliance guidelines included on the FSIS significant guidance documents web page at:

http://www.fsis.usda.gov/OPPDE/rdad/fsisdirectives/10010_1/ecolio157h7dirguid4-13-04.pdf

While control is certainly possible through use of other measures, because FSIS is not as familiar with other practices that might be employed, it will make review of these other measures by an EIAO a priority;

● To capture production practices used by the establishment to control for E. coli O157:H7, and to identify vulnerabilities in the design of the establishment's food safety system;

● To help prioritize whether and when a food safety assessment should be conducted at the establishment; and

● To inform the design and development of the Agency's risk-based verification testing program by ascertaining which establishments to target for more frequent testing.

Before completing the checklist, inspection program personnel should review the training materials on the checklist, particularly as they pertain to the use of prerequisite (purchase specification) programs.

In completing the checklist, please refer to the food safety system on file at the establishment. Complete the checklist for each beef operation establishment. For establishments with multiple shifts in which the production practices differ from one shift to the next, inspection program personnel from each shift should complete the checklist and identify which shift the checklist pertains to.

Periodically, FSIS will ask inspection program to review the responses to the checklist and update the responses, if necessary, to best reflect the production practices

employed by the establishment,

Definition: ***Robust testing*** means that the following features are part of the written program defining how raw beef samples are collected and analyzed:

- For samples capable of excision testing, N-60 represents 375 grams or more of thinly sliced exterior surface tissue (60 slices derived from trim in 5 combo bins/units -- 12 thin slices of exterior surface material from each combo bin/unit); a 375 gram sample is enriched and analyzed using a method at least as sensitive and specific as the FSIS method
- For samples not capable of excision testing (e.g., comminuted product), a composite sample is collected representing all units from a specified time period (10-30 minutes for continuous testing; one sample from the entire production lot; grab samples from each /unit); at least a 65 gram sample is enriched and analyzed using a method at least as sensitive and specific as the FSIS method

A-ESTABLISHMENT INFORMATION

EstabInformation. Please provide the following information. Please enter the establishment information in the following formats: For the date: dd/mm/yyyy; for the establishment number: 00000 M.

Today's date, when the completed checklist is ready to submit: _____

Establishment number: _____

Shift number(s)—mark all that apply if all shifts operate the same: _____

Your name: _____

Was a management official at the establishment provided an opportunity to review the checklist responses:
_____Yes
_____No
_____Don't know

Did the Frontline Supervisor review the checklist responses:
_____Yes
_____No
_____Don't know

To the best of your ability, how long did it take to complete the entire checklist?

_____

B-RAW BEEF FOOD SAFETY SYSTEM

FoodSafetySystem1. What activity does the establishment conduct that may result in product being used as a component in raw ground beef product? Check all that apply.
_____Slaughtering
_____Fabricating
_____Grinding
_____Mechanical tenderizing (blade, needle, pounding, pins, other mechanical device to tenderize)
_____Enhancing (tumbling, massaging, or injecting solutions such as marinade)
_____Other (explain with short description): _____

FoodSafetySystem2. For which raw beef HACCP processing categories does the establishment have a hazard analysis? Check all that apply.
_____Slaughter -- (BP) (03J)
_____Raw product—ground -- (BP) (03B)
_____Raw product—not ground -- (BP) (03C)
_____Product with secondary inhibitors—not shelf stable (explain with short description) — (BP):_____

FoodSafetySystem3. Does the establishment specifically identify *E. coli* O157:H7 as a hazard reasonably likely to occur in the slaughter HACCP processing category?
_____Yes, with a CCP to prevent, eliminate, or reduce to non-detectable level -- (BP)
_____No
_____Don't know

FoodSafetySystem4. Does the establishment specifically identify *E. coli* O157:H7 as a hazard reasonably likely to occur in the raw product--ground HACCP processing category?
_____Yes, with a CCP to prevent, eliminate, or reduce to non-detectable level, and robust testing on finished product -- (BP)
_____No
_____Don't know

FoodSafetySystem5. Does the establishment specifically identify *E. coli* O157:H7 as a hazard reasonably likely to occur in the raw product—not ground HACCP processing category?
_____Yes, with a CCP to prevent, eliminate, or reduce to non-detectable level, and robust testing on production lots containing co-mingled finished product (e.g. combo bins of 2-piece chucks), as well as on production lots containing non-co-mingled primal/sub-primal intended for use as non-intact product -- (BP)
_____No
_____Don't know

FoodSafetySystem6. Does the establishment specifically identify *E. coli* O157:H7 as a hazard **not** reasonably likely to occur in the slaughter HACCP processing category?
_____Yes, with a written sanitation SOP or other prerequisite (purchase specification) program that includes robust testing
_____No
_____Don't know

FoodSafetySystem7. Does the establishment specifically identify *E. coli* O157:H7 as a hazard **not** reasonably likely to occur in the raw product--ground HACCP processing category?
_____Yes, with a written sanitation SOP or other prerequisite (purchase specification) program that includes robust testing – (BP)
_____No
_____Don't know

FoodSafetySystem8. Does the establishment specifically identify *E. coli* O157:H7 as a hazard **not** reasonably likely to occur in the raw product—not ground HACCP processing category?
_____Yes, with a written sanitation SOP or other prerequisite (purchase specification) program that includes robust testing – (BP)
_____No
_____Don't know

FoodSafetySystem9. Does the establishment specifically require a statement (e.g., Certificate of Analysis) from all supplying establishments identifying that at least one validated intervention was effectively applied as intended and as a CCP in the HACCP plan?
_____Yes, for every production lot received, without exception -- (BP)
_____No
_____Don't know

FoodSafetySystem10. Does the establishment specifically require a statement from the supplying establishment stating that the production lot was tested using a robust testing methodology and found to be negative for *E. coli* O157:H7?
_____Yes, for every production lot received from every supplier, including in-house generated source material, without exception -- (BP)
_____No
_____Don't know

FoodSafetySystem11. Does the establishment specifically conduct on-going verification testing in in-coming product for each supplier at a higher frequency during the high prevalence season (April through September) versus the lower frequency months, and collect no fewer than four tests annually for each supplier?

_____Yes -- (BP)
_____No
_____Don't know

FoodSafetySystem12. Does the establishment specifically conduct on-going verification testing of all finished product at least quarterly (e.g., N-60 or composite testing, as appropriate, with proportionally more frequent testing in the high prevalence season months and for the more frequent suppliers)?
_____Yes -- (BP)
_____No
_____Don't know

FoodSafetySystem13. Does the establishment specifically identify the use of an annual third party audit based on their written program requirements?
_____Yes, every supplier at least once annually -- (BP)
_____No
_____Don't know

C-ESTABLISHMENT CATEGORY

EstabCategory1. Please select the specific beef operations conducted at your establishment from the list below (check all that apply).

_____Slaughter
_____Head meat production
_____Cheek meat production
_____Weasand meat production
_____Heart meat production
_____Advanced meat recovery (AMR) production
_____Low temperature rendered lean finely textured beef
_____Partially defatted beef fatty tissue
_____Partially defatted chopped beef
_____Fabrication of primal/sub-primal cuts
_____Bench trim production
_____Mechanical blade tenderizing
_____Mechanical needle tenderizing
_____Mechanical tenderizing by pounding
_____Fabricated steak
_____Enhancing (tumbling, massaging, or injecting solutions such as marinade)
_____Regrind coarse ground product
_____Grinding boneless manufacturing trimmings or other raw ground beef components
_____Patty forming

EstabCategory2. What is the volume of production of each type of product produced (NOTE: Obtain the poundage for the 3 most recent production lots of this type of product produced and record the three figures separately (e.g., use records from the pre-shipment review to obtain the poundage for each production lot; record the poundage and the specifics about the records that were used so that the poundage figure can be verified later, if asked; keep a copy of the on file with this checklist in the government office).

1. 2. 3. Head meat production
1. 2. 3. Cheek meat production
1. 2. 3. Weasand meat production
1. 2. 3. Heart meat production
1. 2. 3. Advanced meat recovery (AMR) production
1. 2. 3. Low temperature rendered lean finely textured beef
1. 2. 3. Partially defatted beef fatty tissue
1. 2. 3. Partially defatted chopped beef
1. 2. 3. Fabrication of primal/sub-primal cuts
1. 2. 3. Bench trim production
1. 2. 3. Mechanical blade tenderizing
1. 2. 3. Mechanical needle tenderizing
1. 2. 3. Mechanical tenderizing by pounding
1. 2. 3. Fabricated steak
1. 2. 3. Enhancing (tumbling, massaging, or injecting solutions such as

marinade)
1. 2. 3. Regrind coarse ground product
1. 2. 3. Grinding boneless manufacturing trimmings or other raw ground beef components
1. 2. 3. Patty forming

EstabCategory3. What is the ***estimated*** volume of production of this type of product produced in a ***day*** for the shift you are reporting on? (NOTE: Make a note of how the estimated volume was derived, identifying the assumptions you made in coming up with this figure; keep a copy of the calculation on file with this checklist in the government office).

_____Slaughter (cattle slaughtered)
_____Head meat production
_____Cheek meat production
_____Weasand meat production
_____Heart meat production
_____Advanced meat recovery (AMR) production
_____Low temperature rendered lean finely textured beef
_____Partially defatted beef fatty tissue
_____Partially defatted chopped beef
_____Fabrication of primal/sub-primal cuts
_____Bench trim production
_____Mechanical blade tenderizing
_____Mechanical needle tenderizing
_____Mechanical tenderizing by pounding
_____Fabricated steak
_____Enhancing (tumbling, massaging, or injecting solutions such as marinade)
_____Regrind coarse ground product
_____Grinding boneless manufacturing trimmings or other raw ground beef components
_____Patty forming

D-BEEF GRINDING

BeefGrind1. If the establishment applies any validated intervention on the ground product, check all that apply.

_____No intervention
_____Organic acid
_____Acidified sodium chlorite
_____Acidified calcium sulfate
_____Irradiation
_____Gaseous ammonia
_____Other(s), please specify: _____
_____Don't know

BeefGrind2. Does the establishment test source materials for *E. coli* O157:H7 prior to grinding? If yes, check all that apply.

_____No
_____One test per lot (lot as defined by the establishment)
_____Robust testing (N-60 or comminuted)
_____Other than robust testing (please specify): _____
_____Don't know

BeefGrind3. Does the establishment test the finished ground beef for *E. coli* O157:H7? If yes, check all that apply.

_____No
_____One test per lot (lot as defined by the establishment)
_____Robust testing (comminuted)
_____Other than robust testing (please specify): _____
_____Don't know

BeefGrind4. What method does the establishment's laboratory use to test ground beef or finished product for *E. coli* O157:H7?

_____FSIS method
_____Other (please specify): _____
_____Don't know

BeefGrind5. How does the establishment group source materials into lots for grinding?

_____Based on 5 combo bins/units
_____Based on combo bins/units from one supplier
_____Based on combo bins/units from suppliers that use validated intervention methods
_____All combo bins/units received in one day
_____Others, please specify: _____
_____Don't know

BeefGrind6. Approximately how many suppliers of trim or other raw ground beef components has the establishment used in the last 30 days?

_____Only from its own slaughter plant
_____1, from other slaughter plant
_____2-3
_____4-6
_____More than 6
_____Don't know

BeefGrind7. Does the establishment use any of the following raw ground beef components in producing ground beef products? If yes, check all that apply.

_____Boneless manufacturing trimmings
_____Bench trim from fabricated primal/sub-primal cuts
_____Bench trim from mechanically tenderized or enhanced primal/subprimal cuts
_____Primal/sub-primal cuts not categorized as boneless manufacturing trimmings (e.g., not specifically intended for grinding)
_____Head meat
_____Cheek meat
_____Weasand meat
_____AMR (Advanced meat recovery) product
_____Low temperature rendered LFTB (lean finely textured beef)
_____Low temperature rendered PDCB (partially defatted chopped beef)
_____Low temperature rendered PDBFT (partially defatted beef fatty tissue)
_____Others (please specify): _____
_____None of the above
_____Don't know

BeefGrind8. Does the establishment knowingly use imported coarse or finely ground beef to produce ground beef products? If yes, check all that apply.

_____No
_____Every production day
_____Weekly
_____Monthly
_____Intermittently
_____Others (please specify): _____
_____Don't know

BeefGrind9. Does the establishment knowingly use imported raw ground beef components other than coarse or finely ground beef to produce ground beef products? If yes, check all that apply.

_____No
_____Every production day
_____Weekly
_____Monthly
_____Intermittently
_____Others (please specify): _____

_____Don't know

BeefGrind10. Does the establishment have documented monitoring or verification procedures to demonstrate that product is maintained at 40 degrees Fahrenheit or below at any of these process steps? If yes, check all that apply.

_____No
_____Receipt of source materials
_____Grinding
_____Storage
_____Distribution
_____Others (please specify): _____
_____Don't know

BeefGrind11. How often does the establishment conduct complete cleaning and sanitizing of equipment and processing areas?

_____After grinding trim or other raw ground beef components from each supplier
_____After grinding trim or other raw ground beef components from a group of suppliers
_____After a sample is collected for *E. coli* O157:H7 testing
_____After each shift
_____Daily after production
_____Less than daily (extended clean-up)
_____Other (please specify): _____
_____Don't know

BeefGrind12. Does the establishment test the product, equipment, or processing area for microbial indicator organisms (e.g., generic *E. coli*, coliforms, APC, Enterobacteriaceae)? If yes, check all that apply.

_____No
_____Beef trim
_____Ground beef product
_____Grinding equipment
_____Processing area
_____Other (please specify): _____
_____Don't know

BeefGrind13. Does the establishment use carryover or rework in which the carryover or rework is specifically accounted for in a robust testing program?
_____Yes
_____No
_____Don't know

E-BEEF TIM FABRICATION

BeefTrimFab1. Does the establishment use one or more of the following cross-contamination controls? If yes, check all that apply.

_____Sanitation of knives and sharpening steels
_____Formulate trim and other raw ground beef components from a sole supplier into the creation of individual production lot
_____Formulate trim and other raw ground beef components from multiple suppliers into the creation of individual production lots
_____Formulate production lots that contains only source material treated to reduce *E. coli* O157:H7 to a non-detectable level (e.g., gaseous ammonia, irradiation)
_____Formulate production lots that contain combinations of source material treated to reduce *E. coli* O157:H7 and source materials not treated to reduce *E. coli* O157:H7
_____None of the above
_____Don't know

BeefTrimFab2. Does the establishment have documented monitoring and verification procedures of the carcass surface temperature maintained below 45 degrees Fahrenheit within 24 hours of slaughter?

_____Yes
_____No
_____Don't know

BeefTrimFab3. Does the establishment apply any validated intervention method, identified in a CCP in the HACCP plan, on the trim and any other raw ground beef component? If yes, check all that apply.

_____No
_____Organic acid
_____Acidified sodium chlorite
_____Acidified calcium sulfate
_____Gaseous ammonia
_____Irradiation
_____Other (please specify): _____
_____Don't know

BeefTrimFab4. Does the establishment test all trim and other raw ground beef components for *E. coli* O157:H7? If yes, check all that apply.

_____No
_____One test per lot (lot as defined by the establishment)
_____Robust testing (comminuted)
_____Other than robust testing (please specify): _____
_____Test purge from one or more combo bins/units
_____Don't know

BeefTrimFab5. Does the establishment use mechanical tenderization methods on

intact beef and use any of this material (e.g., rejects) or the bench trim as a component in raw ground beef?
_____Yes
_____No
_____Don't know

BeefTrimFab6. Does the establishment produce "*specially handled beef manufacturing trimmings"* in this establishment for direct sale and use as ground beef at retail, through a purchase specification arrangement with the retailer?

_____Yes
_____No
_____Don't know

F-BEEF SLAUGHTER

BeefSlaughter1. Does the establishment apply any of the following decontamination procedures to the live or slaughtered cattle prior to hide removal? If yes, check all that apply.

_____No
_____Pre-slaughter animal wash
_____Pre-slaughter head wash
_____Post-slaughter dehairing
_____Pre-dehiding carcass wash
_____Other (please specify): _____
_____Don't know

BeefSlaughter2. Does the establishment apply any of the following full-carcass intervention procedures after hide removal (i.e., not just at limited points on the carcass)? If yes, check all that apply.

_____No
_____Pre-evisceration organic acid rinse
_____Pre-evisceration hot water wash
_____Pre-evisceration steam vacuum
_____Pre-chill organic acid rinse
_____Pre-chill steam treatment
_____Pre-chill steam vacuum
_____Other (please specify): _____
_____Don't know

BeefSlaughter3. Does the establishment have documentation of employee training in any of the following areas of the slaughter operation? If yes, check all that apply.

_____No
_____Proper hide removal
_____Proper evisceration
_____Adequate sanitation of knives and sharpening steels
_____Other (please specify): _____
_____Don't know

BeefSlaughter4. Does the establishment test carcasses for *E. coli* O157:H7 on individual carcasses? If yes, check all that apply.

_____Using the N-60 excision method
_____Swabbing carcass surfaces
_____Other methods, specify_____
_____Don't know

BeefSlaughter5. Does the establishment test for indicator organisms on the hide and/or carcass separate and apart form the regulatory generic *E. coli* test requirement (e.g., generic *E. coli*, coliforms, Enterobacteriaceae) to determine process control? If yes, check all that apply.

_____No
_____Carcass before intervention method
_____Carcass after intervention method
_____Equipment
_____Slaughter area
_____Other (please specify): _____
_____Don't know

BeefSlaughter6. Does the establishment have documented monitoring and verification procedures of the carcass surface temperature maintained below 45 degrees Fahrenheit within 24 hours of slaughter?

_____Yes
_____No
_____Don't know

G-REGRIND COARSE GROUND

RCG1. Does the establishment have purchase specifications requiring that suppliers conduct any of the following as a CCP in the HACCP plan on the pre-coarse ground product or the coarse ground product? If yes, check all that apply.

_____No intervention
_____Organic acid
_____Acidified sodium chlorite
_____Acidified calcium sulfate
_____Irradiation
_____Gaseous ammonia
_____Other(s), please specify: _____
_____Don't know

RCG2. Does the establishment test source materials for *E. coli* O157:H7 prior to grinding? If yes, check all that apply.

_____No
_____One test per lot (lot as defined by the establishment)
_____Robust testing (N-60 or comminuted)
_____Other than robust testing (please specify): _____
_____Don't know

RCG3. Does the establishment test the finished ground beef for *E. coli* O157:H7? If yes, check all that apply.

_____No
_____One test per lot (lot as defined by the establishment)
_____Robust testing (comminuted)
_____Other than robust testing (please specify): _____
_____Don't know

RCG4. What method does the establishment's laboratory use to test coarse ground beef or finished product for *E. coli* O157:H7?

_____FSIS method
_____Other (please specify): _____
_____Don't know

RCG5. How does the establishment group source materials into lots for grinding?

_____Based on 5 combo bins/units
_____Based on combo bins/units from one supplier
_____Based on combo bins/units from suppliers that use validated intervention methods
_____All combo bins/units received in one day
_____Others, please specify: _____
_____Don't know

RCG6. Approximately how many suppliers has the establishment used in the last 30 days?

_____Only from its own slaughter plant
_____1, from other slaughter plant
_____2-3
_____4-6
_____More than 6
_____Don't know

RCG7. Does the establishment knowingly use imported coarse ground beef to produce ground beef products? If yes, check all that apply.

_____No
_____Every production day
_____Weekly
_____Monthly
_____Intermittently
_____Others (please specify): _____
_____Don't know

RCG8. Does the establishment knowingly use imported raw coarse ground beef components to produce ground beef products? If yes, check all that apply.

_____No
_____Every production day
_____Weekly
_____Monthly
_____Intermittently
_____Others (please specify): _____
_____Don't know

RCG9. Does the establishment have documented monitoring or verification procedures to demonstrate that product is maintained at 40 degrees Fahrenheit or below at any of these process steps? If yes, check all that apply.

_____No
_____Receipt of source materials
_____Grinding
_____Storage
_____Distribution
_____Others (please specify): _____
_____Don't know

RCG10. How often does the establishment conduct complete cleaning and sanitizing of equipment and processing areas?

_____After grinding raw ground beef components from each supplier
_____After grinding raw ground beef components from a group of suppliers

_____After a sample is collected for *E. coli* O157:H7 testing
_____After each shift
_____Daily after production
_____Less than daily (extended clean-up)
_____Other (please specify): _____
_____Don't know

RCG11. Does the establishment test the product, equipment, or processing area for microbial indicator organisms (e.g., generic *E. coli*, coliforms, APC, Enterobacteriaceae)? If yes, check all that apply.

_____No
_____Ground beef product
_____Grinding equipment
_____Processing area
_____Other (please specify): _____
_____Don't know

RCG12. Does the establishment use carryover or rework in which the carryover or rework is specifically accounted for in a robust testing program?

_____Yes
_____No
_____Don't know

H-PATTY FORMING

PatForm1. Does the establishment have purchase specifications requiring that suppliers conduct any of the following as a CCP in the HACCP plan on the incoming product? If yes, check all that apply.

_____No intervention
_____Organic acid
_____Acidified sodium chlorite
_____Acidified calcium sulfate
_____Irradiation
_____Gaseous ammonia
_____Other(s), please specify: _____
_____Don't know

PatForm2. Does the establishment test source materials for *E. coli* O157:H7 prior to patty forming? If yes, check all that apply.

_____No
_____One test per lot (lot as defined by the establishment)
_____Robust testing (N-60 or comminuted)
_____Other than robust testing (please specify): _____
_____Don't know

PatForm3. Does the establishment test the finished patties for *E. coli* O157:H7? If yes, check all that apply.

_____No
_____One test per lot (lot as defined by the establishment)
_____Robust testing (comminuted)
_____Other than robust testing (please specify): _____
_____Don't know

PatForm4. What method does the establishment's laboratory use to test patties for *E. coli* O157:H7?

_____FSIS method
_____Other (please specify): _____
_____Don't know

PatForm5. How does the establishment group source materials into lots for patty forming?

_____Based on 5 combo bins/units
_____Based on combo bins/units from one supplier
_____Based on combo bins/units from suppliers that use validated intervention methods
_____All combo bins/units received in one day
_____Others, please specify: _____
_____Don't know

PatForm6. Approximately how many suppliers has the establishment used in the last 30 days?

_____Only from its own slaughter plant
_____1, from other slaughter plant
_____2-3
_____4-6
_____More than 6
_____Don't know

PatForm7. Does the establishment knowingly use imported product for patties? If yes, check all that apply.

_____No
_____Every production day
_____Weekly
_____Monthly
_____Intermittently
_____Others (please specify): _____
_____Don't know

PatFomr8. Does the establishment have documented monitoring or verification procedures to demonstrate that product is maintained at 40 degrees Fahrenheit or below at any of these process steps? If yes, check all that apply.

_____No
_____Receipt of source materials
_____Patty forming
_____Storage
_____Distribution
_____Others (please specify): _____
_____Don't know

PatForm9. How often does the establishment conduct complete cleaning and sanitizing of equipment and processing areas?

_____After patty forming from each supplier
_____After patty forming from a group of suppliers
_____After a sample is collected for *E. coli* O157:H7 testing
_____After each shift
_____Daily after production
_____Less than daily (extended clean-up)
_____Other (please specify): _____
_____Don't know

PatForm10. Does the establishment test the product, equipment, or processing area for microbial indicator organisms (e.g., generic *E. coli*, coliforms, APC, Enterobacteriaceae)? If yes, check all that apply.

_____No
_____Patty product
_____Patty forming equipment
_____Processing area
_____Other (please specify): _____
_____Don't know

PatForm11. Does the establishment use carryover or rework in which the carryover or rework is specifically accounted for in a robust testing program?

_____Yes
_____No
_____Don't know

I-MECHANICAL TENDERIZED

MechTend1. Does the establishment have purchase specifications requiring that suppliers conduct any of the following as a CCP in the HACCP plan on the incoming product? If yes, check all that apply.

_____No intervention
_____Organic acid
_____Acidified sodium chlorite
_____Acidified calcium sulfate
_____Irradiation
_____Gaseous ammonia
_____Other(s), please specify: _____
_____Don't know

MechTend2. Does the establishment conduct any of the following as a CCP in the HACCP plan on the pre-mechanically tenderized product? If yes, check all that apply.

_____No intervention
_____Organic acid
_____Acidified sodium chlorite
_____Acidified calcium sulfate
_____Irradiation
_____Gaseous ammonia
_____Other(s), please specify: _____
_____Don't know

MechTend3. Does the establishment test source materials for *E. coli* O157:H7 prior to mechanical tenderization? If yes, check all that apply.

_____No
_____One test per lot (lot as defined by the establishment)
_____Robust testing (N-60)
_____Other than robust testing (please specify): _____
_____Don't know

MechTend4. Does the establishment test the finished tenderized product for *E. coli* O157:H7? If yes, check all that apply.

_____No
_____One test per lot (lot as defined by the establishment)
_____Robust testing (N-60)
_____Other than robust testing (please specify): _____
_____Don't know

MechTend5. What method does the establishment's laboratory use to test product for *E. coli* O157:H7?

_____FSIS method
_____Other (please specify): _____

_____Don’t know

MechTend6. How does the establishment group source materials into lots for mechanical tenderization?

_____Based on 5 combo bins/units
_____Based on combo bins/units from one supplier
_____Based on combo bins/units from suppliers that use validated intervention methods
_____All combo bins/units received in one day
_____Others, please specify: _____
_____Don’t know

MechTend7. Approximately how many suppliers has the establishment used in the last 30 days?

_____Only from its own slaughter plant
_____1, from other slaughter plant
_____2-3
_____4-6
_____More than 6
_____Don’t know

MechTend8. Does the establishment knowingly use imported product for mechanical tenderization? If yes, check all that apply.

_____No
_____Every production day
_____Weekly
_____Monthly
_____Intermittently
_____Others (please specify): _____
_____Don’t know

MechTend9. Does the establishment have documented monitoring or verification procedures to demonstrate that product is maintained at 40 degrees Fahrenheit or below at any of these process steps? If yes, check all that apply.

_____No
_____Receipt of source materials
_____Mechanical tenderization process
_____Storage
_____Distribution
_____Others (please specify): _____
_____Don’t know

MechTend10. How often does the establishment conduct complete cleaning and sanitizing of equipment and processing areas?

_____After mechanical tenderization from each supplier

_____After mechanical tenderization from a group of suppliers
_____After a sample is collected for *E. coli* O157:H7 testing
_____After each shift
_____Daily after production
_____Less than daily (extended clean-up)
_____Other (please specify): _____
_____Don't know

MechTend11. Does the establishment test the product, equipment, or processing area for microbial indicator organisms (e.g., generic *E. coli*, coliforms, APC, Enterobacteriaceae)? If yes, check all that apply.

_____No
_____Mechanical tenderized product
_____Mechanical tenderization equipment
_____Processing area
_____Other (please specify): _____
_____Don't know

MechTend12. Does the establishment create bench trim in which the bench trim could be used as a raw ground beef component that is specifically accounted for in a robust testing program?

_____Yes
_____No
_____Don't know

MechTend13. Does the establishment provide labeling on the product to inform purchasers that the product is mechanically tenderized (i.e., non-intact)?

_____Yes; specify labeling: _____
_____No
_____Don't know

MechTend14. Approximately how many times does an individual product pass through the mechanical tenderization process?

_____1
_____2-3
_____4-6
_____More than 6
_____Don't know

J-ENHANCED PRODUCT

EnhProd1. Does the establishment have purchase specifications requiring that suppliers conduct any of the following as a CCP in the HACCP plan on the incoming product? If yes, check all that apply.

_____No intervention
_____Organic acid
_____Acidified sodium chlorite
_____Acidified calcium sulfate
_____Irradiation
_____Gaseous ammonia
_____Other(s), please specify: _____
_____Don't know

EnhProd2. Does the establishment conduct any of the following as a CCP in the HACCP plan on the pre-enhanced product? If yes, check all that apply.

_____No intervention
_____Organic acid
_____Acidified sodium chlorite
_____Acidified calcium sulfate
_____Irradiation
_____Gaseous ammonia
_____Other(s), please specify: _____
_____Don't know

EnhProd3. Does the establishment test source materials for *E. coli* O157:H7 prior to enhancing the product? If yes, check all that apply.

_____No
_____One test per lot (lot as defined by the establishment)
_____Robust testing (N-60)
_____Other than robust testing (please specify): _____
_____Don't know

EnhProd4. Does the establishment test the finished enhanced product for *E. coli* O157:H7? If yes, check all that apply.

_____No
_____One test per lot (lot as defined by the establishment)
_____Robust testing (N-60)
_____Other than robust testing (please specify): _____
_____Don't know

EnhProd5. What method does the establishment's laboratory use to test product for *E. coli* O157:H7?

_____FSIS method
_____Other (please specify): _____

_____Don't know

EnhProd6. How does the establishment group source materials into lots for enhancement?

_____Based on 5 combo bins/units
_____Based on combo bins/units from one supplier
_____Based on combo bins/units from suppliers that use validated intervention methods
_____All combo bins/units received in one day
_____Others, please specify: _____
_____Don't know

EnhProd7. Approximately how many suppliers has the establishment used in the last 30 days?

_____Only from its own slaughter plant
_____1, from other slaughter plant
_____2-3
_____4-6
_____More than 6
_____Don't know

EnhProd8. Does the establishment knowingly use imported product for enhanced product? If yes, check all that apply.

_____No
_____Every production day
_____Weekly
_____Monthly
_____Intermittently
_____Others (please specify): _____
_____Don't know

EnhProd9. Does the establishment have documented monitoring or verification procedures to demonstrate that product is maintained at 40 degrees Fahrenheit or below at any of these process steps? If yes, check all that apply.

_____No
_____Receipt of source materials
_____Enhancement process
_____Storage
_____Distribution
_____Others (please specify): _____
_____Don't know

EnhProd10. How often does the establishment conduct complete cleaning and sanitizing of equipment and processing areas?

_____After enhancement from each supplier

_____After enhancement from a group of suppliers
_____After a sample is collected for *E. coli* O157:H7 testing
_____After each shift
_____Daily after production
_____Less than daily (extended clean-up)
_____Other (please specify): _____
_____Don't know

EnhProd11. Does the establishment test the product, equipment, or processing area for microbial indicator organisms (e.g., generic *E. coli*, coliforms, APC, Enterobacteriaceae)? If yes, check all that apply.

_____No
_____Enhanced product
_____Enhancement equipment
_____Enhancement solution
_____Processing area
_____Other (please specify): _____
_____Don't know

EnhProd12. Does the establishment create bench trim in which the bench trim could be used as a raw ground beef component that is specifically accounted for in a robust testing program?

_____Yes
_____No
_____Don't know

EnhProd13. Does the establishment provide labeling on the product to inform purchasers that the product is enhanced (i.e., non-intact)?

_____Yes; specify labeling: _____
_____No
_____Don't know

EnhProd14. How is the enhancement solution labeled regarding name and ingredients?

_____Not applicable
_____Name(s), please specify: _____
_____Ingredient(s), please specify: _____
_____Don't know